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Ethicon Endo-Surgery/Nutter, McClennen & Fish LLP
World Trade Center West
155 Seaport Blvd.
Boston, MA 02210-2604

EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
03/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	**Application No.** 10/677,633	**Applicant(s)** CERIER, JEFFREY C.
	Examiner Julian W. Woo	**Art Unit** 3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-28 and 41-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-28 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 7-10, 42, and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to base claim 7, the specification does not describe at least one through hole of a first biocompatible pledget "having a minimum diameter greater than a maximum diameter of the suture."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 11-13, 15, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards et al. (4,669,473). Richards et al. disclose the invention substantially as claimed. Richards et al. disclose, at least in figures 10-14 and col. 6, line 20 to col. 9, line 23; a tissue fixation device including a suture (e.g., 310), a first biocompatible securing element (315) connected to a first portion of the suture, a second biocompatible securing element (316) connected to a second portion of suture, each of the first and second securing elements being rotatable from a first position during deployment and a second position when deployed, and a deployment instrument with first and second tubes (405, 406), where the first and second securing elements are spaced apart from a third portion of suture (see fig. 13), where a portion of the suture is coupled to another portion of the suture by knotting (see col. 5, lines 50-55 and col. 6, lines 20-22), where the first and second securing elements are generally cylindrical in shape, and are oriented at least substantially parallel to holes in the first position and are oriented at least substantially perpendicular to the holes in the tissue in the second position, and where the first and second securing elements each include a sharp tip and an elongated shape, such that a long axis is larger than a diameter of a tissue hole. However, Richards et al. do not specifically disclose that the second biocompatible securing element is rotatable from a first position to a second position substantially perpendicular to the first position when the tissue fixation device is deployed. Nevertheless, Richards et al. teach, at least in col. 4, line 55 to col. 5, line 6

and col. 5, lines 43-49; that a securing element not only tends to rotate from a first position to a second position substantially perpendicular to the first position, the securing element, when tugged upon during its deployment in tissue, “tends to set the fastener ever deeper into the tissue” (i.e., the securing element, when deployed in tissue, is able to be rotated beyond the nearly-perpendicular angle shown in the figures). In other words, the securing element is indeed rotatable or capable of rotating from first position to second position substantially perpendicular to the first position, when the device is deployed in tissue. In any case, it would be obvious to one having ordinary skill in the art at the time the invention was made, in view of this teaching, to rotate or configure the securing element of Richards et al., so that it is moved or movable from a first position to a second position substantially perpendicular to the first position. Such a modification would ensure firm anchorage of the securing element in tissue, i.e., when the fastener is set deeply into the tissue.

With respect to claim 15 specifically: Richards et al. also disclose, at least in col. 5, lines 50-55 and col. 6, lines 20-22, suture portions coupled together, but do not specifically disclose welding of the suture portions. Nevertheless, claim 15 is construed as a product-by-process claim, and the product (suture) does not depend on the process of making it. The claimed product appears to be the same as the suture of Richards et al. Thus, the suture of Richards et al. is obvious over the claimed (welded) suture.

5. Claims 7-10, 18-21, and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards et al. (4,669,473) in view of McQuilkin et al. (5,219,359).

Richards et al. disclose the invention substantially as claimed. Richards et al. disclose, at least in figures 8-10 and col. 6, lines 6-64; a tissue fixation device including a suture (10B or 310), a first biocompatible or bioimplantable pledget (40B) having at least one through hole, a first portion of the suture (10B) passing through the at least one through hole, a first biocompatible securing element 15B or 315) connected to a portion of the suture, the first securing element being rotatable from a first orientation to second orientation as claimed, where the suture and the first pledget are effective to fix adjacent layer of tissue, where the device includes a second suture (310, see col. 6, lines 20-22) and a second biocompatible securing element (316) connected to a second portion of the suture and rotatable from first and second positions as claimed, and where the sutures and the first and second securing elements comprise biocompatible materials (see col. 6, lines 46-64). However, Richards et al. do not disclose that at least one through hole of the first biocompatible pledget has a minimum diameter greater than a maximum diameter of the suture, nor do Richards et al. disclose a second bioimplantable or bioimplantable pledget having at least one through hole, where a first portion of the second suture passes through a second through hole in the first pledget or where two end of suture are passed through through holes of the first and second pledgets, where both ends are disposed on the same side of the first pledget. McQuilkin et al. teach, at least in the figures, first and second bioimplantable pledgets (30, 32) each including a plurality of through holes (302, 304) for receiving first and second suture portions or ends (24, 22), where the through holes have a minimum diameter greater than a maximum diameter of the suture (e.g., see figs. 1 and 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McQuilkin et al., to include first and second bioimplantable pledgets as claimed with the suture or suture portions and securing elements of Richards et al., and it would have been obvious to modify the diameter of at least one through hole in the first pledget and/or the diameter of the suture or suture portions of Richards et al., so that the diameters are configured as claimed. Such modifications would allow the device of Richards et al. to be quickly positioned about tissue and to effectively clamp and/or support organ tissue without undue tissue damage, as exemplified in figures 10-12 of McQuilkin et al.

6. Claims 16, 17, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards et al. (4,669,473) in view of Bonutti (5,845,645). Richards et al. disclose the invention substantially as claimed. Richards et al. disclose, in col. 11, lines 22-26; securing elements separably attachable to suture portions, which in turn, are coupled together. However, Richards et al. do not disclose suture portions passing through openings in the first and second securing elements and suture that is endless or forms a closed loop. Bonutti teaches, at least in figure 6 and col. 3, lines 22-29; a securing element (20) including through openings (40, 42) for receiving two legs (48, 50) of suture configured to be coupled to tissue or other devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Bonutti, to modify the securing elements and suture portions of Richards et al., so that securing elements include through openings and so that the suture portions comprise suture legs coupled together to form an endless suture or a closed loop. Such

modifications would allow the securing elements to be positively rotated and secured within tissue by suture legs, while suture legs coupled to other suture legs (to form an endless suture or closed loop) would allow doubling of the suture used to hold tissue and ensure that the tissue is held or anchored with less risk of breakage of the tensioned suture.

Response to Amendment

7. Applicant's arguments with respect to claims 7-28 and 41-44 have been considered but are either moot in view of new ground(s) of rejection or are not persuasive. With respect to arguments regarding the rejection of claims 7-10, 18-21, 42, and 43 and based on Richards et al. and McQuilken et al.: McQuilken et al. also provide a teaching regarding the through hole of a pledget, where the through hole has a minimum diameter greater than a maximum diameter of a suture. This teaching was applied to modify the pledget and/or suture of Richards et al. With respect to arguments regarding the rejection of claims 41 and 44 and based on the Richards et al.: Richards et al. indeed teach or suggest first and second securing elements each having a “proximal end configured for removable attachment to an instrument.” First, Webster's II New Riverside University Dictionary defines "attach" to include "to fasten on or affix to: connect or join." Then given the broadest reasonable interpretation of the related term "attachment," indeed, a securing element of Richards et al. is removably attached, i.e., connected or joined, to tool 100 as seen in figs. 2 and 3. That is, the attachment or connection of the securing element to the tool is brought about by the element’s

containment within sheath 105, by the element’s contact with plunger 110, and by the suture's contact with and bending within slot 130 of the sheath.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773